(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 June 2002 (20.06.2002)

PCT

(10) International Publication Number
WO 02/47742 A2

(51) International Patent Classification[7]: A61M

(21) International Application Number: PCT/US01/46776

(22) International Filing Date:
10 December 2001 (10.12.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/256,083 15 December 2000 (15.12.2000) US

(71) Applicant *(for all designated States except US)*: **ALSIUS CORPORATION** [US/US]; 15770 Laguna Canyon Road, Suite 150, Irvine, CA 92618 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **NODA, Wayne** [US/US]; 28072 Paseo Rincon, Mission Viejo, CA 92692 (US).

(74) Agents: **ALONZO, Arlyn**; ALSIUS CORPORATION, 15770 Laguna Canyon Road, Suite 150, Irvine, CA 92618 et al. (US).

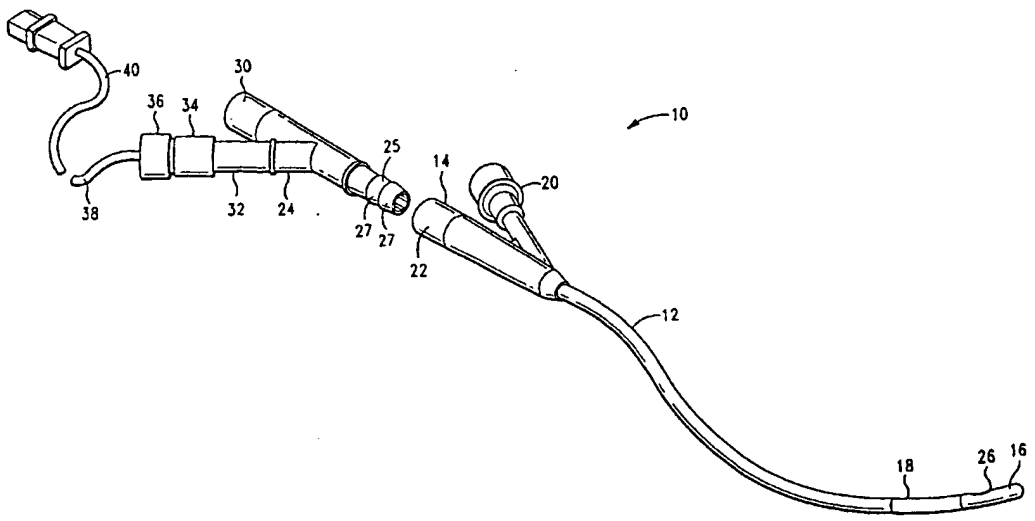
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: TEMPERATURE SENSOR ADAPTER FOR FOLEY CATHETERS



(57) Abstract: The present invention includes an adapter for advancing a temperature sensor through the drainage lumen of an operational Foley catheter. The Foley catheter includes a catheter body having proximal end, a distal end and a drainage lumen extending between the ends. A balloon mounts on the distal end for holding the catheter in the bladder of a patient. The adapter attaches to the proximal end for inserting a temperature sensor via the catheter drainage lumen to the distal end of the catheter. This adapter enables a typical Foley catheter to achieve a temperature sensing capability and provides collocated sensor elements in Foley catheters having a single temperature sensor element. Such temperature sensor measurements are useful, for example, in conjunction with various heat exchange catheter systems.

WO 02/47742 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

TEMPERATURE SENSOR ADAPTER FOR FOLEY CATHETERS

FIELD:

This invention relates to Foley Catheters, and particularly Foley Catheters having temperature sensors.

INCORPORATION BY REFERENCE:

The disclosures of US Patent No. 6,019,783, issued February 1, 2000, US Patent No. 6,126,684, issued October 3, 2000, and US Patent No. 6,146,411, issued November 14, 2000, are incorporated herein by reference.

BACKGROUND:

Foley catheters typically include a soft, thin rubber tube with a balloon on one end. The catheter is threaded through the urinary duct (urethra) and into the bladder to drain urine from the bladder. A Foley catheter is typically used when normal urination is disrupted by an infection, a swollen prostate gland, bladder stones, or, sometimes, an injury. In very sick people, a catheter may be used to keep track of urine production.

A typical Foley catheter has drainage lumen, and an inflation lumen for inflating and deflating the balloon. The balloon is normally deflated until properly positioned in a patient's bladder. Once the catheter is properly positioned, the inflation lumen delivers fluid to inflate the balloon. The inflated balloon holds the catheter in place.

There are risks associated with the use of a Foley catheter. For example, the bladder or urethra could be injured when the Foley catheter is inserted. Infection is also possible. Patients may find the process of insertion of a Foley catheter unpleasant and sometimes painful.

The bladder is an accepted situs for core body temperature measurements. Accordingly, some Foley catheters include a temperature sensor included on the end of the catheter. A wire connects the sensor, via the catheter, to externally located monitoring devices.

One drawback to Foley catheters with a temperature sensor is that the sensor may fail. When the sensor fails, the failed catheter may have to be replaced. This not only compounds patient discomfort, but also increases the risk of injury and infection for the patient.

What is desired is a way to measure a patient's core body temperature while minimizing patient discomfort and risk of injury. What is also desired is a way of assuring redundancy and accuracy in core body temperature measurements.

SUMMARY:

The adapter of the present invention attaches to the drainage lumen of a standard Foley catheters, including Foley catheters having integrated temperature sensors. The adapter is generally "Y" shaped, having a drainage lumen in communication with the catheter drainage lumen, and a temperature sensor lumen with a temperature sensor.

The adapter has a threaded fitting fixed on the adapter temperature sensor lumen for sealing the temperature sensor lumen and for anchoring the temperature sensor. The adapter has a threaded cap and a seal. The seal seats in the adapter and the threads of the cap join with the threads of the fitting to actuate the seal.

The temperature sensor includes a sensor element disposed distally on the temperature sensor, and a wire. The wire extends from the sensor element through the fitting.

The cap compresses the seal against the fitting when the cap attaches to the adapter. Accordingly, the fitting prevents leakage and anchors the temperature sensor wire with respect to the adapter.

BRIEF DESCRIPTION OF THE DRAWINGS:

FIG. 1 is a perspective view of a Foley catheter and the adapter in accordance with the present invention.

FIG. 2 is a perspective view of a Foley catheter inserted into a patient and the adapter in accordance with the present invention.

FIG. 3 is a cross-sectional view of the catheter body as seen along the line 3-3 in FIG. 2.

FIG. 4 is an exploded cross-sectional view of the cap and fitting in accordance with the present invention.

FIG. 5 is a cross-sectional view of the cap operatively engaged with the fitting as seen along the line 4-4 of FIG. 2.

DESCRIPTION:

FIG. 1 shows a Foley catheter generally designated with the reference numeral 10. The catheter 10 includes a catheter body 12 with a proximal end 14 and a distal end 16. The catheter 10 also includes a balloon 18, an inflation lumen 20, a drainage lumen 22, and an adapter 24.

The balloon 18 is deflated for insertion into a patient. The balloon 18 is disposed near the distal end 16. The inflation lumen 20 extends within the catheter body 12 from the proximal end 14 to the balloon 18, in fluid communication with the balloon 18, for inflating and deflating the balloon 18.

The catheter drainage lumen 22 extends from the proximal end 14 to the distal end 16. The distal end 16 includes an opening 26 in fluid communication with the drainage lumen 22 to facilitate drainage of urine from the bladder of a patient.

The adapter 24 has a drainage lumen 30, a temperature sensor lumen 32 and a connector 25. The connector 25 attaches to the proximal end 14 of the catheter body 12. The connector 25 establishes fluid communication between the adapter drainage lumen 30 and the catheter drainage lumen 22. Preferably the connector 25 is tapered and includes ribs 27 for insertion and press-fit into the proximal end 14 of the catheter body 12.

The adapter temperature sensor lumen 32 includes a fitting 34 and a cap 36. The temperature sensor 38 has a wire 40 and a distally located sensor element 33 (FIG. 2). The fitting 34 is fixed on the temperature sensor lumen 32 of the adapter 24. Preferably the fitting 34 bonds to the temperature sensor lumen 32. The fitting 34 receives the cap 36. The cap 36 and a portion of the fitting 34 are threaded to enable the cap 36 to rotate onto the fitting 34. The cap 36 is rotatable to adjustably torque the cap 36 onto the fitting 34.

The temperature sensor wire 40 normally slides through the cap 36, the fitting 34, the connector 25, and the catheter drainage lumen 22. The temperature sensor 38 includes a distally mounted temperature sensor element 33 (FIG. 2) that seats in the distal end 16 of the catheter body 12. Rotating the cap 36 with respect to the fitting 34 selectively anchors the wire 40 with respect to the adapter 24 to prevent movement of the sensor element 33.

FIG. 2 shows the Foley catheter 10 inserted into the bladder 42 of a patient. The Foley catheter 10 includes an integrated temperature sensor 46 with an integrated sensor element 35 disposed at the distal end 16 of the catheter body 12.

During normal operation of the Foley catheter 10, the catheter 10 is introduced into the bladder 42 of a patient. The balloon 18 inflates to hold the catheter 10 in the bladder 42. Urine drains from the bladder 42 through the opening 26 and via the catheter drainage lumen 22. The integrated sensor 46 with the sensor element 35 senses the patient's bladder temperature.

The adapter 24 attaches to the proximal end 14 of the catheter body 12. An operator manually advances the temperature sensor wire 40 to slide the temperature sensor wire 40 and sensor element 33 via the drainage lumen, towards the distal end 16 of the catheter body 12. Preferably, the temperature sensor wire 40 slides the temperature sensor element 33 fully to the distal end 16 of the catheter body 12.

According to one method of using the invention, the integrated temperature sensor 46 fails. This failure is detected. The Foley catheter 10 remains in the bladder 42. The adapter 24 of the present invention then attaches to the proximal end 14 of the catheter and the sensor 38 with the sensor element 33 advances through the drainage lumen of the Foley catheter 10 to position the sensor element 33 in the distal end 16 of the catheter body 12.

The sensor element 35 and the sensor element 33 are collocated for redundancy and improved accuracy. The sensor elements 33 and 35 provide a primary and secondary measure, respectively, of core body temperature. The secondary measure of temperature is used in conjunction with primary temperature measurements for improved temperature sensing accuracy and reliability.

Collocated temperature sensor elements 33 and 35 are also useful for communicating with discrete monitoring and data compilation devices requiring temperature input, such as a discrete patient data recorder and a medical device, for examples.

It can be appreciated that sensor collocation may not be required in some systems. For example, when a patient normothermia is desired, and an intravascular temperature regulator is used on the patient, it may be desirable to have multiple temperature sensors in various parts of the body (including the bladder) to optimally determine the patient core body temperature and communicate that body temperature to the intravascular temperature regulator.

According to one aspect of the invention, the temperature adapter 24 and Foley catheter 10 are used in conjunction with vascular heat exchange catheter such as disclosed in copending US Patent Application No. 09/220,897, the disclosure of which is incorporated herein by reference. It can be appreciated that core body temperature measurements are important to facilitate proper functioning of any system that regulates the core body temperature of a patient. Accordingly, redundant bladder temperature measurements with collocated sensor elements 33 and 35, is desirable to minimize any risk or inconvenience associated with temperature monitoring failure.

Foley catheters can be used to drain urine for several weeks. An integrated temperature sensor 46, may fail during this period. The method, thus, enables an introduced Foley catheter having a failed integrated temperature sensor 46 to be used continuously for draining urine notwithstanding failure of the integrated temperature sensor 46. The steps of maintaining the catheter 10 in the bladder 42 and attaching the adapter 24 to the proximal end 14 and advancing the adapter temperature sensor 38 provides a secondary measure of temperature without requiring the unpleasant steps of removal and replacement of the Foley catheter 10.

FIG. 3 shows the catheter body 12 having three lumens, the inflation lumen 20, the drainage lumen 22, and an integrated temperature sensor lumen 48. The temperature sensor lumen 48 houses the wire 46 of the integrated temperature sensor 46. The wire 40 of the adapter temperature sensor 38 is positioned freely in the drainage lumen 22.

FIG. 4 shows the cap 36, the fitting 34 and a seal 56. The cap 36 has internal threads 50 and the fitting 34 has external threads 52. The cap 36 has an axis and includes an axially disposed post 54. The seal 56 seats within the fitting 34. The post 54 defines a portion of a channel 58. The channel 58 extends axially through the cap 36, the fitting 34 and the seal 56. The temperature sensor wire 40 normally slides through the channel 58 when the cap 36 and the fitting 34 loosely engage, or disengage.

According to an aspect of the invention, the seal 56 is generally cylindrical in shape and circumscribes the wire 40. The wire 40 is lubricated to facilitate sliding when the cap 36 loosely fits on the fitting 34.

The fitting 34 defines an annular flange 62 so that when the cap 36 threads on to the fitting 34, the post 54 of the cap 36 presses the seal 56 against the annular flange 62. Rotation of

the cap 36 with respect to the fitting 34 deforms the seal 56, which grips the wire 40 and thereby selectively anchors the wire 40 with respect to the cap 36 and the fitting 34.

FIG. 5 shows the cap 36 engaging the fitting 34. The cap 36 rotates to compress the seal 56 against the flange 62. The seal 56 circumscribes the wire 40 so that compressing the seal 56 anchors the wire 40.

IN USE:

An anticipated use for the invention described herein is in conjunction with a patient temperature regulation system having a heat exchange catheter. A system having a heat exchange catheter is described generally in US Patent No. 6,019,783, the disclosure of which is incorporated herein by reference. A feedback loop between the temperature sensor of the Foley catheter and the patient temperature regulation system is established.

A typical patient temperature regulation system includes an venous catheter having a heating and/or cooling element. The catheter inserts into a patient's central venous system to warm and/or cool the blood. The warmed/cooled blood circulates within the patient to effect the patient core body temperature. In accordance with the present invention, the core body temperature is measured using a Foley catheter and adaptor as described herein.

A heat exchange catheter is described in US Patent Nos. 6,146,411 and 6,126,684, the disclosures of which are incorporated herein by reference. One heat exchange catheter includes lumens for circulating heat exchange fluid within the catheter. This creates a closed system heat exchanger so that circulation of heat exchange fluid within the catheter cools/warms the blood of the patient. A system employing the heat exchange catheter has a temperature measurement device and a control unit. The control unit regulates the rate of flow of the heat exchange fluid as well as the temperature of the fluid. A feedback loop established between the Foley catheter-based temperature sensor elements of the present invention is used to regulate the heat exchange fluid temperature of the closed system, and the rate of heat exchange fluid flow.

While the present invention is anticipated to be used in conjunction with a patient temperature regulation system, it can be appreciated that it can be used in any of a number of systems. For example, the present invention can be used in virtually any surgical procedure requiring a measurement of a patient's core body temperature.

It can also be appreciated that the seal 56 may take many forms, including that of an o-ring. Notwithstanding the form of the seal 56, the relative movement of the cap with respect to the seal 56 deforms the seal 56 to anchor the wire 40. It can be appreciated that the seal 56 need not simply seat in the fitting 34, the seal may also be formed as part of the fitting 34, or the cap 36. The fitting 34 may be discrete, or integrated with the temperature sensor lumen 32 of the adapter 24. Accordingly, the present invention should be limited only by the claims as set forth below.

CLAIMS:

What is claimed is:

1. An adapter connectable with the drainage lumen of a Foley catheter, comprising:

a connector attachable to the drainage lumen of a Foley catheter, the adapter having a drainage lumen, and a temperature sensor lumen with a fitting;

a temperature sensor having a wire;

a means for sealing the wire within the adapter; and

a means for selectively anchoring the wire within the adapter.

2. An adapter as set forth in claim 1, wherein the means for sealing includes a cap and a seal attachable to the adapter, the wire passes through the cap and seal.

3. An adapter as set forth in claim 2, wherein the fitting defines an annular flange, the cap compresses the seal against the annular flange to anchor the wire with respect to the adapter and for sealing the wire within the adapter.

4. An adapter as set forth in claim 3, wherein the seal is generally cylindrical in shape and circumscribes the wire.

5. An adapter as set forth in claim 3, wherein the adapter and the cap are threaded.

6. An adapter as set forth in claim 3, wherein the adapter and the cap are threaded, the cap rotatably attaches to the adapter so that rotation of the cap compresses the seal.

7. An adapter as set forth in claim 3, wherein the cap includes an axially disposed post, the post compresses the seal when the cap rotates onto the fitting.

8. An adapter as set forth in claim 1, wherein the adapter attaches to the drainage lumen of a Foley catheter having a catheter body with a distal end, the temperature sensor includes a sensor element disposed in the distal end.

9. An adapter connectable with the drainage lumen of a Foley catheter, comprising:

a connector attachable to the drainage lumen of a Foley catheter, the adapter having a drainage lumen and a temperature sensor lumen;

a fitting attached to the temperature sensor lumen;

a temperature sensor having a wire, the temperature sensor wire extending through the fitting; and

a cap with a threaded interior, the fitting being threaded to enable the threads of the cap to join with the threads of the fitting, the cap including an opening to enable the wire to pass through the cap.

10. An adapter as set forth in claim 9, wherein the fitting defines an annular flange and the cap includes a seal, the cap presses the seal against the annular flange when the cap rotates.

11. An adapter as set forth in claim 9, wherein the fitting defines an annular flange and the cap includes a seal, the cap presses the seal against the annular flange when the cap rotates, the seal circumscribes the wire.

12. An adapter as set forth in claim 11, wherein the seal is generally cylindrical in shape.

13. An adapter as set forth in claim 11, wherein the cap includes an axially disposed post.

14. An adapter as set forth in claim 11, wherein the cap includes an axially disposed post, the post defines an opening to enable the wire to pass through the post.

15. An adapter as set forth in claim 14, wherein the post compresses the seal when the cap rotates.

16. A Foley catheter having a temperature sensor adapter, comprising:

a catheter body with a proximal end and a distal end,

an inflatable balloon disposed near the distal end,

an inflation lumen extending from the proximal end to the balloon for inflating and deflating the balloon;

a drainage lumen extending from the proximal end to the distal end;

an adapter connectable with the proximal end of the catheter body and in fluid communication with the drainage lumen, the adapter includes a drainage lumen and a temperature sensor lumen;

a fitting attached to the adapter temperature sensor lumen; and

a temperature sensor having a wire and a sensor element, the sensor element being disposed in the distal end of the catheter body and the wire extending through the catheter body drainage lumen and through the fitting.

17. A Foley catheter having a temperature sensor adapter as set forth in claim 16, wherein the fitting defines an annular flange and the adapter includes a cap and a seal, the cap presses the seal against the annular flange to anchor the wire when the cap rotates.

18. A Foley catheter having a temperature sensor adapter as set forth in claim 16, wherein the fitting defines an annular flange and the adapter includes a cap and a seal, the cap presses the seal against the annular flange when the cap rotates, the seal defines a opening to enable the wire to pass through the seal.

19. A Foley catheter having a temperature sensor adapter as set forth in claim 16, wherein the fitting defines an annular flange and the adapter includes a cap and a seal, the cap presses the seal against the annular flange when the cap rotates, the seal circumscribes the wire.

20. A Foley catheter having a temperature sensor adapter as set forth in claim 19, wherein the seal is generally cylindrical in shape.

21. A Foley catheter having a temperature sensor adapter as set forth in claim 19, wherein the cap includes an axially disposed post.

22. A Foley catheter having a temperature sensor adapter as set forth in claim 19, wherein the cap includes an axially disposed post, the post defines an opening to enable the wire to pass through the post.

23. A method of using a temperature sensor adapter with a Foley catheter, comprising:

introducing a Foley catheter into the bladder of a patient, the Foley catheter includes catheter body with a proximal end, a distal end a drainage lumen extending between the proximal end and the distal end for draining urine from the bladder;

draining urine from the bladder via the drainage lumen;

attaching an adapter having a temperature sensor to the proximal end of the catheter body; and

advancing the temperature sensor towards the distal end of the catheter via the drainage lumen to sense temperature within the bladder.

24. A method as set forth in claim 23, wherein the step of advancing the temperature sensor includes sliding the temperature sensor to the distal end of the catheter body.

25. A method as set forth in claim 23, wherein the step of introducing precedes the steps of attaching and advancing.

26. A method as set forth in claim 23, wherein the step of introducing includes:

providing a Foley catheter with an integrated temperature sensor;

detecting failure of the integrated temperature sensor;

maintaining the catheter in the bladder;

attaching the adapter to the proximal end; and

advancing the adapter temperature sensor.

27. A method as set forth in claim 23, wherein the Foley catheter includes a balloon positioned at the distal end and an inflation lumen, the method includes inflating the balloon via the inflation lumen to hold the catheter in the bladder.

28. A method as set forth in claim 23, wherein the temperature sensor includes a wire that extends through the drainage lumen of the catheter and the adapter when the sensor advances, the method further comprises sealing the wire.

29. A method as set forth in claim 23, wherein the temperature sensor includes a wire and the method includes lubricating the wire.

30. A method as set forth in claim 23, wherein the temperature sensor includes a wire, the method further comprises anchoring the wire to hold the temperature sensor in the drainage lumen.

31. A method as set forth in claim 30, wherein the adapter includes a cap, a seal, a fitting with an annular flange and a temperature sensor lumen, the fitting being integrated with the temperature sensor lumen of the adapter, the seal seats against the annular flange when the cap attaches to the adapter, the seal defines a channel to enable the wire to pass through the seal, the wire passes through the seal wherein, the step of anchoring the wire includes attaching the cap to the adapter.

32. A method as set forth in claim 30, wherein the adapter includes a cap with a seal, a fitting with an annular flange and a temperature sensor lumen, the fitting being integrated with the temperature sensor lumen of the adapter, the cap and the temperature sensor lumen are threaded;

the method includes seating the seal against the annular flange when the cap attaches to the adapter; defining an channel within the seal to enable the wire to pass through the seal; passing the wire through the seal; and the step of anchoring the wire includes threading the cap to the adapter and rotating the cap with respect to the adapter to deform the seal and anchor the wire.

33. A method for measuring and regulating patient temperature comprising:

introducing a heat exchange catheter into the vasculature of a patient;

introducing a Foley catheter into the bladder of the patient;

draining urine from the bladder via the drainage lumen;

attaching an adapter having a temperature sensor to the proximal end of the Foley catheter; and

advancing the temperature sensor towards the distal end of the catheter to sense temperature within the bladder.

34. The method as set forth in claim 33, further comprising establishing a feedback loop between the temperature sensor and the heat exchange catheter for regulating patient core body temperature.

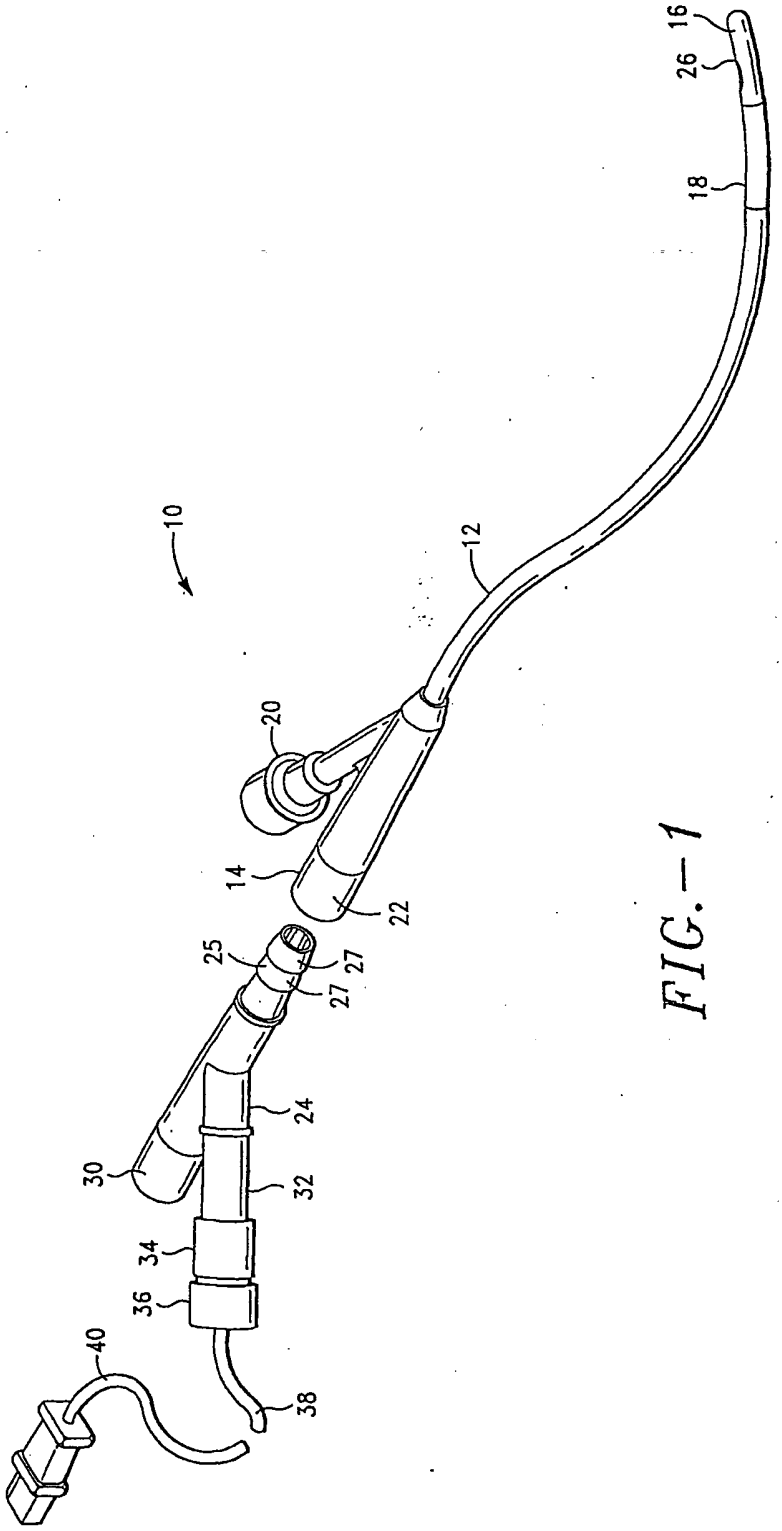


FIG. – 1

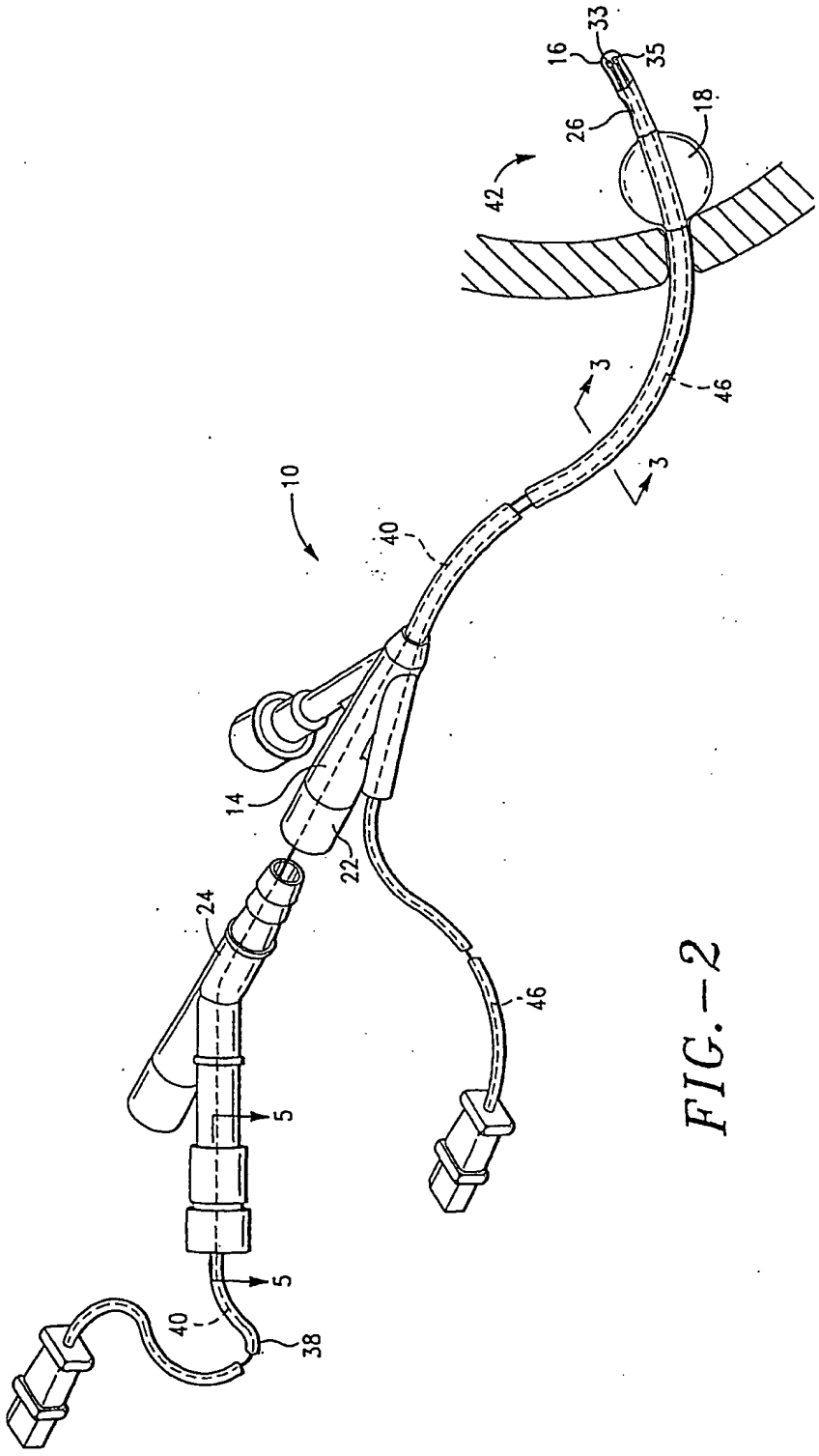


FIG.-2

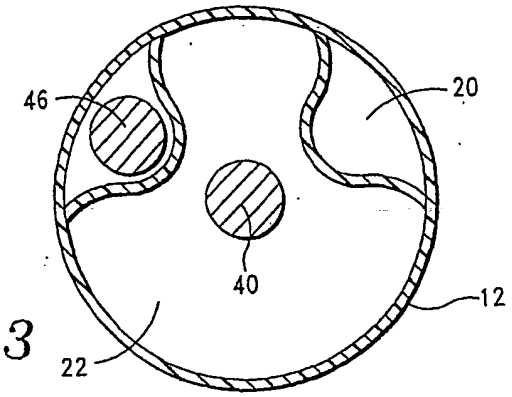


FIG.–3

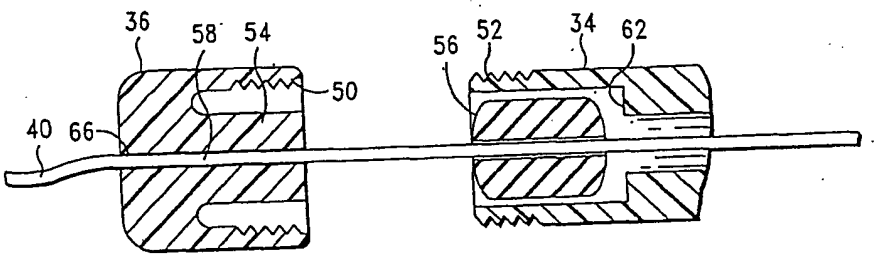


FIG.–4

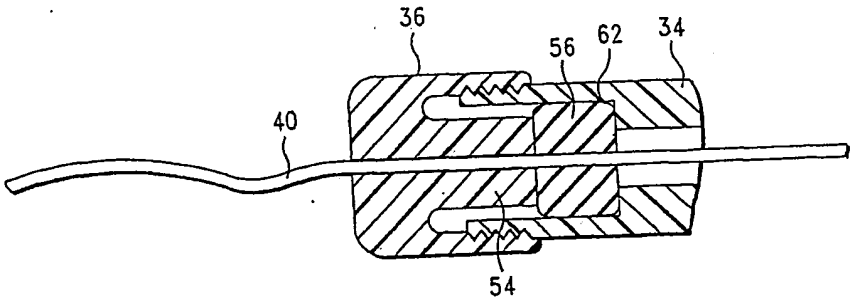


FIG.–5